Exhibit 1

EXPERT REPORT

Analysis of Distributor Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances on behalf of Lake and Trumbull Counties, Ohio

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Prepared by
James E. Rafalski
37637 Five Mile Road #278
Livonia, MI 48154

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chargeback data, customer files, internal and external communications to include emails, written correspondence, and notes.

- Administrative investigation resulted in an Administrative Memorandum of Agreement that remained in effect for three years.

As a DEA Diversion Investigator with 13 years of experience (2004-2017), I am uniquely qualified to offer expert opinions regarding compliance with federal regulations governing the distribution of controlled substances including oxycodone and hydrocodone. I am familiar with the DEA Diversion Investigators Manual and received training from the United States Department of Justice on suspicious order monitoring, data analysis from ARCOS, reporting of suspicious orders and the due diligence required before shipping an order flagged as suspicious. I directly participated in the successful prosecution of Masters Pharmaceutical which resulted in a case opinion from the highest federal court in the country (to date). I led the first action that led to a memorandum of agreement with a manufacturer for failure to maintain effective controls to prevent diversion and failing to design and operate an adequate suspicious order monitoring system.

Based (a) on my education, training and experience, (b) the law, regulation and practices in the area of CSA enforcement, and (c) on my review of document and testimony provided in this case (MDL 2804), I am of the opinion to a reasonable degree of professional certainty that there was a systematic, prolonged failure over many years by the distributor/pharmacy defendants to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market.[1] I am further of the opinion that this systematic failure was a substantial cause of the opioid epidemic plaguing the country and specifically in Lake County and Trumbull County. I am prepared to testify regarding the regulatory duties imposed by the CSA and federal regulations. I have been asked to review the documents produced by the defendants and depositions taken in MDL2804 and other opioid litigation that I have been asked to provide opinions in and offer opinions regarding statutory and regulatory compliance.

I offer my opinions herein to a reasonable degree of professional certainty. I believe the facts stated herein are true and accurate and based on the record provided to me. I understand that the defendants continue to supplement discovery and have disclosed hundreds of thousands of documents. I have relied upon the defendants' answers to discovery requests as a basic outline for evidence of compliance to reach my opinions.

I am being compensated at the rate of $300.00 per hour for the time I have spent related to this report. The hourly rate for my time spent testifying is $500.00 per hour. I have not previously provided expert testimony at trial. I have provided expert testimony by deposition in *In re: National Prescription Opiate Litigation*, MDL No. 2804 (Case Track One and Case Track Two) and in the New York State litigation, *In re Opioid Litig.*, Index No. 400000/2017. I have not authored any publications or articles. In addition to the documents and testimony cited within my report, I have also reviewed documents identified in the attached Schedule I.

[1] I provide all opinions in this report with a reasonable degree of professional certainty.

II. OPINIONS

Based on my education, background, experience, and review of the documents produced in this matter and provided to me, my opinions, which are more fully set forth throughout this report, are as follows:

1. The Controlled Substance Act (CSA) is designed to provide for a closed delivery system related to the pharmaceutical supply chain. The CSA requires DEA registration for each member of the closed supply chain, known as a registrant. This is due to the dangerous and abusive nature of the controlled substances that flow through the pharmaceutical supply chain.

2. As a member of the closed delivery system each registrant takes on certain statutory and regulatory obligations to ensure the safety and efficiency of the pharmaceutical supply chain. These statutory and regulatory duties have remained the same sense the enactment of the CSA.

3. The pharmaceutical supply chain flows from manufacturer (labeler) to wholesale distributor and then to the end dispenser (pharmacy, hospital, practitioner). This gives the distributors a unique position in the supply chain in that they are the last checkpoint before the controlled substances go to the end dispenser.

4. Under the CSA and the implementing regulations the distributors have two significant obligations that are designed to ensure that these controlled substances do not veer outside of the closed supply chain. These statutory and regulatory obligations come from:

    - 21 U.S.C.A. § 823(b)(1); which requires the "maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."

    - 21 C.F.R. § 1301.74(b); which require the registrant to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." Then the registrant is required to notify the DEA of all identified suspicious orders prior to shipment.

5. Each of these obligations play a vital role in protecting the integrity of the pharmaceutical supply chain. It is up to each registrant to design a system, often referred to as a suspicious order monitoring system (SOMS), that will comply with these regulatory requirements based on the differing type of business models they choose as customers. For example, a wholesale distributor that only services hospitals would need a SOMS different from that for one who services veterinary clinics.

6. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to develop and implement a SOMS that would ensure the maintenance of effective controls against diversion. While each of them had different systems for which they implemented each of these systems were either faulty in their design or in the manner they were operated.

7. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to develop a comprehensive system to monitor, detect, and report all suspicious orders of opioids placed by pharmacies in Lake and Trumbull Counties. This failure is exacerbated as there were significant timeframes when the Defendants would identify suspicious orders and still ship the orders to the respective pharmacies.

8. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to conduct adequate due diligence on suspicious orders of opioids placed by pharmacies in Lake and Trumbull Counties, to determine whether the customer was engaged in diversion;

9. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each distributed opioids to pharmacies in the Lake and Trumbull Counties in disproportionately excessive amounts without adequately documenting justification; and

10. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to halt suspicious shipments of opioid orders to pharmacies in Lake and Trumbull Counties they knew, or should have known, were going to be diverted.

III. STANDARDS

A. STATUTORY DUTY.

Each distributor/pharmacy owes a duty to ***maintain effective control*** against diversion of prescription opiates into the illicit market. 21 U.S.C.A. § 823(b)(1) [1970].

The Controlled Substances Act ("CSA") and its implementing regulations create restrictions on the distribution of controlled substances. *See* 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009). The main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. The CSA categorizes all controlled substances into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. The CSA

and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.[2]

The CSA authorizes the DEA to establish a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market.[3] Any entity that seeks to become involved in the production or chain of distribution of controlled substances must first register with the DEA.[4]

The CSA provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain ***illegal***.[5] "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic."[6]

Distributors of Schedule II drugs—controlled substances with a "high potential for abuse"[7] – must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[8] The CSA is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs. **Such a closed system is intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[9] The CSA seeks, through appropriate regulation of the manufacture and distribution of drugs, to reduce the availability of drugs subject to abuse except through legitimate channels of trade and for legitimate uses.[10]

Based on my review of all the relevant documents and testimony taken in this case (MDL 2804) it is my opinion to a reasonable degree of professional certainty that the multiple distributors servicing Lake County and Trumbull County failed to maintain effective control against diversion

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[2] *Gonzales v. Raich*, 545 U.S. 1, 12–14 (2005) (internal citations omitted).

[3] H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970); *see* 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880.

[4] 21 U.S.C. § 822; 21 C.F.R. § 1301.11.

[5] 1970 U.S.C.C.A.N. 4566, 4569 (emphasis added).

[6] *United States v. Moore*, 423 U.S. 122, 135 (1975).

[7] 21 U.S.C. §§ 812(b), 812(2)(A)-(C)

[8] 21 U.S.C. § 823(b)(1).

[9] 1970 U.S.C.C.A.N. 4566, 4571-72.

[10] 1970 U.S.C.C.A.N. 4566, 4574.

of prescription opiates into other than legitimate medical, scientific, and industrial channels in violation of 21 U.S.C.A. § 823(b)(1).

B. REGULATORY DUTY

Each distributor "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[11]

This regulatory duty has been defined to include the following obligations:

> The "***security requirement***" at the heart of this case mandates that distributors "design and operate a system" to identify "suspicious orders of controlled substances" and report those orders to DEA (the ***Reporting Requirement***). 21 C.F.R. § 1301.74(b). The Reporting Requirement is a relatively modest one: It requires only that a distributor provide basic information about certain orders to DEA, so that DEA "investigators in the field" can aggregate reports from every point along the legally regulated supply chain and use the information to ferret out "potential illegal activity." *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007). Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some "due diligence" and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the ***Shipping Requirement***).[12]

The regulatory duty is not difficult to follow and understand. An entity who voluntarily applies to become a registrant must submit an application and undergo a pre-registration investigation. The pre-registration investigation involves a thorough onsite inspection of the registrant's facilities as well as extensive instructions on the applicable regulations and the security requirements that must be followed. While there are numerous requirements related to registration, my opinions focus on the following compliance requirements:

- Maintain effective controls to prevent the diversion of controlled substances into "other than legitimate medical, scientific, and industrial channels";
- "Design and operate" a system to identify suspicious orders; and
- Report suspicious order "when discovered."

C. MDL2804 Discovery Ruling 12

[11] 21 C.F.R. § 1301.74(b) [1971]

[12] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212–13 (D.C. Cir. 2017) (emphasis added).

prescription opiates.[115] It is worth noting that these guidelines relate to "Listed Chemicals", rather than Schedule II and III controlled substances, primarily focused on the sale of chemicals used to make illicit methamphetamine. "Suspicious orders" of Listed Chemicals are defined by 21 USC § 830(b)(1)(A) as orders of "extraordinary" size [based on a formula which generally multiples a monthly base weight average per base code by a multiplier (3x)]. Notably, the Chemical Handlers Manual also mandates:

> **When a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions. In addition to making required reports, the transactions should not be completed until the customer is able to eliminate suspicions.**[116]

Relying upon a threshold of "extraordinary" size fails to detect orders of "unusual size" and is not compliant with 21 CFR 1301.74(b). Nor is shipping suspicious orders after reporting. Further, reliance on this threshold also does not detect orders of unusual pattern or frequency.

M. MAINTENANCE OF EFFECTIVE CONTROLS AGAINST DIVERSION OF CONTROLLED SUBSTANCES

Registrants engaged in actively distributing controlled substances must implement measures to comply with the legal and regulatory requirements. These measures should be documented as a standard operating policy for the company and be distributed to all relevant employees. These standardized policies should be designed by distributors and manufacturers to take the utmost precautions to prevent diversion by maintaining the "closed system" of distribution. Included below are some key components that one would expect to see an operational system designed to maintain effective controls against diversion.

- Registrants must have a comprehensive system in place and conduct an investigation on a customer who will be purchasing controlled substances. The following are some of the activities utilized to establish a new customer:
    - The review to establish a new customer and begin distribution of controlled substances is a critical first step to ensures a potential customer has a business plan consistent with compliance with the Controlled Substances Act. The review should confirm the information provided by the potential customer is accurate. One commonly used procedure by distributors is to utilize a customer questionnaire which asks a series of questions similar to the following:
        - Past history of DEA registration to determine compliance history
        - Check of state and local licensure compliance.
        - Compliance history with state medical/pharmacy board
        - Review the business plan to determine legitimacy of the customer

[115] *See*, *e.g.*, CAH_MDL_PRIORPROD_HOUSE_0002207; CAH_MDL_PRIORPROD_DEA07_01198690.

[116] CAH_MDL_PRIORPROD_DEA07_01198690, 01198713.

distibutors, such as those considered in this report, have total visibility of all orders placed by their affiliated pharmacies to any distributor. Therefore chain pharmacy distributors must consider and take into account orders placed to third-party distributors when determining whether orders from affiliated pharmacies are suspicious. The suspicious order monitoring system failures described above directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances. These orders never should have shipped until after the suspicion of diversion was dispelled.

IV. Identifying Suspicious Orders Distributed in Lake and Trumbull Counties, Ohio

I have described in this report the ways in which the defendants' inadequate response to their statutory and regulatory requirements to maintain effective controls related to the sales of prescription opioids would potentially cause the diversion of these pills for non-medical use. I have reviewed seven suspicious order methodologies, some of which were utilized by one or more of the defendants. These methodologies are identified in the April 16, 2021 report of Craig J. McCann, Ph.D., CFA as "Maximum Monthly, Trailing Six-Month Pharmacy Specific Threshold," "Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold," "Twice Trailing Twelve-month Average," "Three Times Trailing Twelve-month Average," "Maximum 8,000 Dosage Units Monthly," "Maximum Daily Dosage Units," and "Maximum Monthly Trailing Six Month Specific Threshold on Rolling 30 Days." Dr. McCann applied these methodologies to each defendant's dsitributions of opioids into Lake and Trumbull County as well as, separately, to opioid orders from all distributors to each defendant's affiliated chain pharmacies. The purpose of each system was to identify suspicious orders that should not have been shipped unless the distributors' due diligence eliminated the suspicion of diversion. Each method would have identified a significant volume of orders of opiates as shown in the tables below.[118]

With the exception of the methodology titled Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold,[119] under each of these methodologies, once an order by a pharmacy is flagged and the distributor does not conduct sufficient due diligence to dispel the suspicion of diversion, each subsequent order by that pharmacy is also flagged. The failure to conduct adequate due diligence on the initial triggering order, means that all subsequent orders by that pharmacy are likewise suspicious. This is consistent with the testimony of Thomas Prevoznik

[118] I utilized these Defendants - CVS, Walgreens, Walmart, HBC/Giant Eagle, and Rite Aid - as they constitute a significant majority of the opioid pills delivered into CT3 according to the data described in the Expert Report of Craig J. McCann.

[119] Under the Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold, when a transaction causes the number of dosage units shipped to a pharmacy in a month to exceed the highest number of dosage units shipped to the pharmacy in any one of the six preceding months, the dosage units of highest month in the preceding six months becomes threshold which is then applied in all subsequent months.

Enforcement Administration, 861 F.3d 206 (2017) provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size.[124] *See* Methodology A above. Pursuant to *Masters,* "as a matter of common sense and ordinary language, orders that deviate from a six-month trend are an 'unusual' and not 'normal' occurrence" *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 216 (D.C. Cir. 2017). I say this understanding that this litigation will be advanced by selecting a methodology quantifying a volume of pills that entered CT3 jurisdictions unlawfully and providing this data to an economist to measure the harm caused by this volume.

Based on my education, background, and experience, as well as my review of relevant documents, the absence of adequate distributor due diligence and failure to respond to indicators of suspicious orders as described in this report constitutes the Defendants' failures to comply with the requirements of the Controlled Substances Act. It is further my opinion that this misconduct led to the excess quantity of opiate pills flooding the illicit market in CT3 jurisdictions.

V. REGISTRANT SUSPICIOUS ORDER MONITORING SYSTEMS (SOMS)

I have been asked to review the documents produced in this litigation to determine whether the distributors complied with the statutory and regulatory duties outlined above. In this process I have reviewed numerous documents and depositions for each of the enumerated Defendants. Based on my review it is my opinion to a reasonable degree of professional certainty that each of the distributors failed to comply with their statutory and regulatory duty to maintain effective controls to prevent diversion and to design and operate a system to identify and report suspicious orders.

A. CVS Health

Distribution Center	DEA Registrant Number
CVS Indiana, L.L.C. 7590 Empire Drive, Doors 116-123 Indianapolis, Indiana 6219	RH0197170
CVS Rx Services, Inc. 150 White Wagon Road Chemung, New York 14825	RC0415871
CVS TN Distribution, L.L.C. 10017 Kingston Pike Knoxville, Tennessee 37922	PR0205559

Transactional Data:

Date range: 2006-2014 (ARCOS)

Volume:

[124] This approach does not take into consideration unusual pattern or frequency.

8. **Shipping Requirement:**

Despite representing to its upstream vendors that it screened and stopped suspicious shipments from shipping, Giant Eagle did not have the ability to automatically stop orders from shipping which exceeded its set threshold during the period that Giant Eagle shipped controlled substances.[700]

Giant Eagle also did not manually stop suspicious orders from shipping which had been flagged by its threshold report. Giant Eagle admitted that its threshold reports tracked already shipped, not ordered materials,[701] which did not leave an adequate window or process to identify, stop and investigate unusual orders once it became aware of them.

After Giant Eagle stopped shipping prescription opioids through HBC, it had the opportunity for GERX DC to utilize a third-party system to stop over-threshold orders from shipping. Giant Eagle's Senior Pharmacy Director Adam Zakin declined, claiming it was not worth the expense because the only thing the new system would do was "stop the orders physically if there were a threshold."[702]

By:

James Rafalski
April 16, 2021

[700] HBC_MDL00029196; ENDO_HSGAC_0007618 at -0007621; HBC_MDL00169476; Tsipakis 12/13/18 Depo., 213:8–10, 255:24–256:23; HBC_MDL00028498.

[701] Tsipakis 12/13/18 Depo., 141:3–11.

[702] HBC_MDL00028498, email, March 29, 2016.